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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,413	03/30/2001	Shigeru Yamamoto	Q63731	8678

7590 08/19/2004
Sughrue Mion Zinn
Macpeak & Seas
2100 Pennsylvania Avenue NW
Washington, DC 20037

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,413

Applicant(s)

YAMAMOTO ET AL.

Examiner

David J Steadman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 11, 13, 14 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 22 is/are allowed.
- 6) ☒ Claim(s) 1-3, 11, 13, 14 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Status of the Application

- [1]** Claims 1-4, 11, 13-14, and 22-26 are pending in the application.
- [2]** Applicants' amendments to the claims, filed May 13, 2004 and June 22, 2004, are acknowledged. The listing of the claims filed June 22, 2004 replaces all prior versions and listings of the claims in the instant application.
- [3]** Applicants' amendment to the specification, filed May 13, 2004, is acknowledged.
- [4]** Applicants' arguments filed May 13, 2004 and June 22, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [5]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Specification/Informalities

- [6]** The objection to the specification for the use of trademarks is maintained (see item [6] of the Office action mailed January 13, 2004). It appears that applicants have made a *bona fide* attempt to amend the specification to overcome the objection. However, applicants have not capitalized the trademarks as suggested in the previous Office action. See MPEP 608.01(v).

Claim Rejections - 35 USC § 112, First Paragraph

[7] Claims 1-2, 11, 13-14, and 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1 (claims 2 and 23-24 dependent therefrom) and 11 (claims 13-14 and 25-26 dependent therefrom) recite the alleged highly stringent hybridization conditions of "6X SSC, 0.1% SDS, and 68°C," referring to page 70 for support for this newly added limitation. However, it is noted that the examiner can find no support for the recited conditions at page 70 of the specification. It is suggested that applicants direct the examiner's attention to specific supporting disclosure for the recited conditions in the specification, claims, or drawings as originally filed.

[8] The scope of enablement rejection of claims 1-3, 11, 13-14, and 23-26 under 35 U.S.C. 112, first paragraph, is maintained for those reasons set forth in item [12] of the Office action mailed January 13, 2004, and for the reasons of record.

[9] RESPONSE TO ARGUMENTS: Applicants argue the function of the claimed polypeptide, *i.e.*, "activity to act upon a disaccharide glycoside to thereby release saccharides from said disaccharide glycoside in a disaccharide unit, wherein said disaccharide glycoside has a glucose moiety at the aglycon side" is not overly broad in scope as the diglycosidase from *Aspergillus fumigatus* as well as from other

microorganisms listed in claim 1 have been shown to act on any disaccharide glycoside that has a glucose moiety at the aglycon side.

The examiner acknowledges that the specification indicates that the diglycosidase from *Aspergillus fumigatus*, i.e., the polypeptide of SEQ ID NO:2, and the cell extracts of the bacterial strains disclosed at page 45 of the specification have a broad substrate specificity with respect to the disaccharide glycoside that is hydrolyzed (see pp. 71-73 and 76 of the specification).

Applicants argue the specification provides guidance for making and using the full scope of claimed or recited polypeptides. Applicants argue the full scope of claimed or recited polypeptides can be made by routine methods that would not require undue experimentation. Applicants' argument is not found persuasive.

In this case, the claims are not so limited to a polypeptide isolated from the bacterial strains disclosed at page 45 of the specification. Instead, the claims broadly encompass a polypeptide isolated from any of the genera of microbes as recited in claims 1 and 11. Even assuming *arguendo* claims 1 and 11 were limited to a polypeptide isolated from those microbial strains listed at page 45 of the specification, it is noted that, if given their broadest reasonable interpretation in accordance with MPEP 2111, the claims broadly encompass mutant and variant polypeptides that meet the structural and functional limitations recited in the claims. For example, the scope of polypeptides encompasses mutant and variant polypeptides that are endogenously expressed by strains of the recited microbes that can be generated by, for example, UV and/or chemical mutagenesis. Moreover, the claims encompass recombinantly

expressed mutants and variants of a diglycosidase enzyme that are expressed and purified from the recited microbial strains that have been used as host cells for recombinant protein expression. While it is acknowledged that the scope of polypeptides must exhibit all structural and physico-chemical characteristics as recited in the claims, the scope of claimed polypeptides broadly encompasses insertion, deletion, addition, and/or substitution mutants and variants as long as the polypeptide is isolated from the recited microbial strains, including mutants and variants generated by UV/chemical mutagenesis or recombinant methods. The examiner's position is supported by the specification, which states, "mutants of the strains having diglycosidase productivity, or various microorganisms... ..modified by recombinant DNA techniques to have an ability to produce diglycosidase... ..are also included in the production method which can be used in the present invention" and goes on to state that the gene or polynucleotide encoding the diglycosidase can be a variant (see, *e.g.*, pp. 12-13, 16-17, and 20 of the specification). However, the specification fails to provide guidance for making diglycosidase mutants and variants as broadly encompassed by the claims, *e.g.*, amino acids or regions of the polypeptide of SEQ ID NO:8 or the diglycosidase polypeptides of the genera of microbes encompassed by the claims where alterations to the sequence can be made with an expectation of obtaining a polypeptide having the desired activity/utility. Without such guidance, it is highly unpredictable as to the amino acid(s) of a given polypeptide that can be altered without disrupting the activity of the parent polypeptide. This high level of unpredictability is evidenced by the teachings of Branden et al. (cited in a previous Office action), which

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are exemplified by Witkowski et al. (*Biochemistry* 38:11643-11650), who disclose that a single amino acid substitution results in conversion of the parent polypeptide's activity from a beta-ketoacyl synthase to a malonyl decarboxylase (see e.g., Table 1, page 11647). While methods of altering a protein sequence were known in the art at the time of the invention, it was not routine to screen for all variants of a given protein as encompassed by the scope of the claims. At least for the reasons stated above, the specification does not enable the full scope of claimed or recited polypeptides.

Conclusion

[10] Status of the claims:

- Claims 1-4, 11, 13-14, and 22-26 are pending.
- Claims 4 and 22 appear to be in a condition for allowance.
- Claims 1-3, 11, 13-14, and 23-26 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 3:30 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

ACJ 08-13-04